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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,861	03/16/2001	Tsafrir S. Mor	BTI-45	6166

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EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 02/27/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/810,861	MOR ET AL.
	Examiner	Art Unit
	Georgia L. Helmer	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 January 2003.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 8-12 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7 and 13-15 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

## DETAILED ACTION

### ***Restriction election and Status of the Claims***

1. The Office acknowledges the receipt of Applicant's restriction election, Paper No. 11, filed 29 January 2003. Applicant elects Group I, claims 1-7, 13 -15 as drawn to SEQ ID NO: 4, with traverse. Applicant traverses stating that Groups II and I are not distinct. Applicant's traversal has been considered and is unpersuasive because Groups II and I are distinct because the Group II methods include methods to make physiologically active human acetylcholinesterase, which product can be made by a different process, that of in vitro systems to produce the human acetylcholinesterase. Groups III and I are distinct for reasons of record; methods of treatment using human acetylcholinesterase are different from methods of expressing a polynucleotide in a plant. The supplemental restriction, Paper No 10, dated 13 January 2003, is withdrawn. This restriction is made Final.
2. Claims 1-15 are pending. Claims 1-7, 13 14 and 15 are examined in this office action. Claims 8-12 are withdrawn as drawn to nonelected inventions.

### ***Information Disclosure Statement***

3. A signed copy of Applicant's IDS form 1449, Paper No. 3 filed 16 July 2001, is included.

### ***Claim Rejections - 35 USC § 101***

4. Claims 2, 4 and 5 are rejected under 35 U.S.C. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2, 4 and 5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims are drawn to regenerable cells, seed and pollen of plant cells comprising a human acetylcholinesterase polynucleotide. However, since the cells, seed and pollen have not been subject to selection, they will not necessarily contain the transgene. Therefore these claims read on wild-type cells, seed and pollen, which is non-statutory subject matter.

***Claim Rejections - 35 USC § 112-second***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 6, "physiologically active" is unclear because the activity of the physiological activity claimed is not described. The metes and bounds of this claim are not defined. "tissue type" is unclear, what does this mean?

Clarification and/or correction are required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for plant cells, does not reasonably provide enablement for any cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims any transformed cell. Applicant teaches a transformed plant cell.

Simple heterologous expression constructs in plant host systems are clearly structurally different from heterologous expression constructs in other host systems, including mammalian, yeast and bacterial systems. Required are different promoters, enhancers, codon optimization, termination regions, and other regulatory regions. One of skill in the art would expect a heterologous expression system constructed for plant cells to differ from one functional in a non-plant cell.

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The claims are drawn to any cell, including, mammal, any yeast and any bacteria. While non-plant cells have been extensively used to express heterologous constructs, the constructs must be recognized by the cell machinery. Otherwise, the construct would be degraded or removed from the cell. No construct to date is universally recognized in all cells. One skilled in the art would expect that a expression system encoding a human acetylcholinesterase construct for plant cell would also differ from such an expression system for a bacteria cell, a yeast cell, a insect cell and a mammalian cell.

Applicant does not disclose an expression system encoding a human acetylcholinesterase of the instant application universally adapted to be operable in all cell types. Applicant has only shown that Applicant's expression system encoding a human acetylcholinesterase is operable in plant cells. It is unpredictable that Applicant's expression system encoding a human acetylcholinesterase would be operable in all cell types. Accordingly, Applicant has only enables Applicant's expression system encoding a human acetylcholinesterase for a plant cell. Thus Applicant is not enabled for using an expression system encoding a human acetylcholinesterase in any cell type, as commensurate in scope with the claims.

***Claims Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13 and 14 rejected under 35 U.S.C. 102(b) as being anticipated by Soreq, et al, US 5,595,903, issued 21 January 1997.

Soreq teaches a synthetic polynucleotide comprising a nucleic acid molecule that encodes a human acetylcholinesterase (Claim 1) and a host cell comprising human acetylcholinesterase (claims 3, 4, and 6).

Accordingly, Soreq anticipates the claimed invention.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or  
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Soreq et al, US 5,891,725, issued 6 April 1999.

Soreq teaches SEQ ID NO: 5, which is SEQ ID NO: 7 of US 5, 891,725.

Accordingly, Soreq anticipates the claimed invention

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 1-7 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soreq as applied to Claims 13-15 above, and further in view of Goodman, et al, US 4,956,282, issued 11 September 1990.

The teachings of Soreq are discussed above. Soreq does not teach transgenic plant cells, plants, tomato, or seed.

Goodman teaches expressing physiologically active mammalian proteins in plant cells (col 10, lines 11-17), tissue cultured cells (col 5, lines 34-46), transgenic plants (col 4, lines 55-59), seed (col 4, lines 61-62) and tomato plants (col 4, lines 57-60).

Goodman does not teach human acetylcholinesterase.

One skilled in the art would have been motivated at the time of the invention to substitute for the mammalian gene of Goodman, the human acetylcholinesterase of Soreq, with a reasonable expectation of success. Motivation for this was the knowledge that providing alternative production systems for producing physiologically active peptides was desirable (Goodman, col 1, lines 38-46).

Accordingly, the claimed invention is prima facie obvious in view of the prior art.

**Remarks**

13. No claim is allowed.
14. SEQ ID NO: 5 is known in the prior art.
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD  
Patent Examiner,  
Art Unit 1638  
February 23, 2003

  
ELIZABETH F. MC ELWAIN  
PRIMARY EXAMINER  
GROUP 1600